

**Pharmaceutical Management Branch  
Cancer Therapy Evaluation Program, DCTDC, NCI**

**Investigational Drug Returns  
Policy and Procedures**

**Policy:**

Investigators/Designees should make every effort to minimize the amount of drug ordered and returned unused, (e.g. limit inventories to an 8 week supply or less).

Investigators/Designees should return unused DCTDC supplied investigational agent to the NCI clinical repository when:

- The agent is no longer required because the study is completed or discontinued and the agent cannot be transferred to another DCTDC sponsored protocol. Whenever possible DCTDC supplied investigational agents should be transferred to another DCTDC sponsored trial that utilizes the same investigational agent, form and strength. All policies and procedures regarding investigational drug transfer should be followed.
- Agent is outdated. Investigators/designees should only return outdated agents with a firm expiration date or if they have received written notification from PMB that an agent has expired and should be returned.
- The drug is damaged or unfit for use. Investigators/designees should contact the PMB prior to returning investigational agents because of stability concerns, (e.g. loss of refrigeration or exposure to elevated temperatures). Do **NOT** return broken vials. Broken vials should be destroyed at the clinical site. Follow the appropriate drug accountability guidelines.

**General Guidelines:**

- Regulations require that all agents returned to the DCTDC, NCI be destroyed.
- Return only unused vials/bottles. Do **NOT** return opened or partially used vials/bottles.
- Return only DCTDC supplied agents to the NCI Clinical Repository. Do **NOT** ship drugs from other sources to the NCI clinical repository.

**Procedure:**

- Complete the Return Drug List (attached). All information must be accurate and complete, (e.g. protocol numbers and investigator numbers).
- Double check quantities and lot numbers prior to shipment.
- All instructions on the Return Drug List must be followed.
- Enclose the Return Drug List with the returned drugs. Keep a copy for your records.
- Package the drugs securely to prevent breakage. Breakage of vials on route to the NCI Clinical Repository is a potential health hazard. To minimize the risk to couriers and the NCI Clinical Repository staff, we recommend that all return drugs be double bagged.
- Ship drug returns at room temperature. Refrigerated shipment is not required.
- Send drug returns to the address indicated on the Return Drug List.
- Express delivery (e.g. next day air) is NOT necessary for drug returns.
- The investigator/designee is responsible for the cost of shipment. "Collect" or C.O.D. shipments will **NOT** be accepted.

- Return receipt - Investigators/designees must complete the return receipt section of the Return Drug List if they want confirmation of a drug return.

August 12, 1996